UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,490	03/12/2004	Karl Bruce Thor	046562/274661	8365

826 7590 03/25/2008

ALSTON & BIRD LLP
BANK OF AMERICA PLAZA
101 SOUTH TRYON STREET, SUITE 4000
CHARLOTTE, NC 28280-4000

EXAMINER	
HUYNH, CARLIC K	

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
03/25/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/799,490	THOR, KARL BRUCE	
	Examiner	Art Unit	
	CARLIC K. HUYNH	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *11 and 12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 13-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of applicants' amendments and remarks filed on December 19, 2007 is acknowledged.

Status of the Claims

1. Claims 1-21 are pending in the application, with claims 11-12 having been previously withdrawn from consideration, in response to the restriction requirement filed on May 17, 2007. It is noted claims 22-43 have been cancelled in an Amendment—After Non-Final Rejection filed on December 19, 2007. Accordingly, claims 1-10 and 13-21 are being examined on the merits herein.

The Objections to the Specification for use of trademarks and to claim 1 have been withdrawn in view of Applicants' amendments.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. Claims 1-10 and 13-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poss et al. (US 6,225,324) in view of Childers et al. (US 6,469,007).

Poss et al. teach a method of inhibiting re-uptake of endogenous serotonin that is also effective in the treatment of depression comprising the oral administration of compounds of formula (I) (column 3, lines 1-8; column 12, lines 30-34; and column 13, line 7). Poss et al. also teach the compounds used for treating depression may be administered individually or as mixtures with other therapeutic agents (column 13, lines 17-19). Furthermore, Poss et al. teach dosage forms of tablets and caplets (column 13, line 26).

Poss et al. do not specifically teach a method of treating sexual dysfunction, when to administer the active agent, controlled or delayed dosage forms, and effervescent tablets.

Childers et al. teach piperazine derivatives used for the treatment of depression such as by the potentiation of serotonin reuptake inhibitors and sexual dysfunction (abstract and column 7, lines 4-6 and 12). Childers et al. also teach administration of the piperazine derivatives 0.5, 2, and 4 hours prior to administration of the 5-HT_{1A} agonist 8-OH-DPAT (column 6, lines 30-21 and Table 4).

To a person of skill in the art at the time of the invention, it would have been obvious to employ the antidepressant agent of formula I of Poss et al. to be used in a method for treating sexual dysfunction because the piperazine derivatives of Childers et al. are piperazine derivatives

used to treat depression and according to Childers et al., the piperazine derivatives used to treat depression can also be used to treat sexual dysfunction.

The motivation to combine the composition of Poss et al. to the compounds of Childers et al. is that the compounds of Childers et al. are antidepressants that are also useful as a treatment for sexual dysfunction.

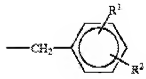
Regarding controlled release dosage form as recited in instant claim 8, Childers et al. teach tablet-disintegrating agents, which meets the limitations of the instant claims (column 7, lines 49-50). Childers et al. teach a number of tablet-disintegrating agents that could yield the controlled release dosage form that is recited in instant claim 8. It would obvious that the tablet-disintegrating agents taught by Childers et al. are controlled release dosage forms.

Regarding delayed release dosage form as recited in instant claim 9, Childers et al. teach tablet-disintegrating agents, which meets the limitations of the instant claims (column 7, lines 49-50). Childers et al. teach a number of tablet-disintegrating agents that could yield the delayed release dosage form that is recited in instant claim 9. It would obvious that the tablet-disintegrating agents taught by Childers et al. are delayed release dosage forms.

Regarding effervescent tablet as recited in instant claim 16, Childers et al. teach tablet-disintegrating agents, which meets the limitations of the instant claims (column 7, lines 49-50). Childers et al. teach a number of tablet-disintegrating agents that could yield the rapidly disintegrating effervescent tablet that is recited in instant claim 16. It would obvious that the tablet-disintegrating agents taught by Childers et al. are effervescent tablets.

Regarding the active agent as recited in instant claim 21, Poss et al. teach a compound of formula I, which meets the limitation of the compound in the instant claim 21 (column 3, lines 1-

8 and 20-28). The compound in instant claim 21 is the compound in 1(a) where Z is a phenyl substituted with 2 alkoxy, namely methoxy, groups and Y is:



, where R_1 is hydrogen and R_2 is a halogen, namely bromine.

Response to Arguments

3. Applicants' arguments, see "Remarks" filed on December 19, 2007, with respect to "Rejections under 35 U.S.C. § 103" to claims 1-10 and 13-21 have been fully considered and are not persuasive.

Applicants argue Poss et al. (US 6,225,324) teaches substituted-benzyl or substituted-indolyl cyclic amino- substituted N-aryl or heteroaryl cyclic amines that act as selective serotonin reuptake inhibitors (SSRIs), which inhibit the reuptake of serotonin into presynptic neurons. Applicants further argue Childers et al. (US 6,469,007) teach piperizine compounds that are 5-HT_{1A} receptor antagonists, which act to increase the amount of serotonin released from presynaptic neurons.

In response, Examiner notes that Poss et al. and Childers et al. both teach compounds that are mechanistically different but have the same function, which is to increase the amount of serotonin in the synapse. Poss et al. teaches substituted-benzyl or substituted-indolyl cyclic amino- substituted N-aryl or heteroaryl cyclic amines that act as selective serotonin reuptake inhibitors (SSRIs), which inhibit the reuptake of serotonin into presynptic neurons thereby increasing the amount of serotonin in the synapse (column 3, lines 1-8; column 12, lines 30-34;

and column 13, line 7). Childers et al. teach piperizine compounds that are 5-HT_{1A} receptor antagonists, which act to increase the amount of serotonin released from presynaptic neurons thereby increasing the amount of serotonin in the synapse (abstract and column 7, lines 4-6 and 12). Moreover, Childers et al. teaches a method of treating depression that is potentiated by serotonin reuptake inhibitors, which can also be used to treat sexual dysfunction (column 7, lines 4-5 and 12).

Thus the Rejections under 35 U.S.C. § 103 to claims 1-10 and 13-21 have been maintained.

Conclusion

4. No claims are allowable.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlic K. Huynh whose telephone number is 571-272-5574. The examiner can normally be reached on Monday to Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gollamudi S Kishore, Ph.D/
Primary Examiner, Art Unit 1612

ckh